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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/828,838	KLADAKIS ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/4/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-14,16-27, 29-34* is/are pending in the application.

4a) Of the above claim(s) *29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-14,16-27 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response and amendments filed 4 October 2007 are acknowledged and entered. Claims 9, 15, and 28 have been cancelled by Applicant. New claims 32-34 have been added. Claims 1-8, 10-14, 16-27, and 29-34 are pending. Claims 29-31 remain withdrawn as being drawn to non-elected inventions. Claims 1-8, 10-14, 16-27, and 32-34 are under examination.

Response to Arguments

Claim Objections/Rejections Withdrawn

2. The objection to claim 1 because of informalities is withdrawn in light of Applicant's amendment.

3. Rejections over claims 9, 15, and 28 are withdrawn as moot in light of Applicant's cancellation of the claims.

4. The rejection of claims 1-8, 10-14, and 16-27 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn in light of Applicant's amendments.

5. The rejection of claims 1-8, 10-14, 17 and 18 under 35 U.S.C. 102(b) as anticipated by Bowman et al. (U.S. Pregrant Publication US 2002/0127265, 12 September 2002), as exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243), is withdrawn in light of Applicant's amendments.

6. The rejection of claims 1-8, 10-14, 16-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of Applicant's amendments.

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-8, 10-14, and 16-27 remain rejected and new claims 32-34 are rejected under 35 U.S.C. 103(a) as being obvious over Bowman et al. U.S. Patent Publication US 20020127265 (12 September 2002), in view of Huckle et al., WO 01/85226 (published 15 November 2001), and exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243).

Applicant argues that the claim amendments overcome the instant rejections (p. 13, third and fourth paragraphs). Applicant argues that the '265 publication does not teach a dry laid scaffold (Remarks, p. 10, next to last paragraph and p. 13, first paragraph). Applicant argues that the '265 publication does not teach viable tissue "disposed" on the tissue repair scaffold (Remarks, p. 11, first paragraph). Applicant argues that WO 01/85226 does not teach viable tissue "disposed" on the tissue repair scaffold (p. 12, last three paragraphs). Applicant's arguments have been fully considered, but they are not persuasive.

Applicant has amended claims 1 and 19 to recite that the scaffold comprises a "high density dry laid" nonwoven polymeric material. Paragraph 8 of the specification generically sets forth a preferred embodiment for a "high density" nonwoven material (p.2). However, no definition of "high density" is set forth in the specification. Although the specification does not specifically set forth a definition of "high density," the teachings in the specification do provide a range of densities such that a "high density" application may be relatively determined. For example, a scaffold comprising 65/35 PGA/PCL foam component mated with a PDS nonwoven material having a density of 60 mg/cc and a thickness of 1mm is taught at paragraph 88 (p. 20). The suture tests for this scaffold are illustrated in Figures 6A and 6B. Figures 6A and 6B show the initial max load of N greater than 6 and initial stiffness of N about 1.5. From Figures 6A and 6B, it appears that a density of 60 mg/cc would meet the requirements for a "high density" nonwoven material, in light of the recitation in claims 1 and 19 because claims 1 and 19 also recite that the scaffold has an initial suture pull out strength (max load) of greater than about 6N and an

initial modulus of elasticity (stiffness) of about 1.5 Mpa. It is also noted that page 9 of the specification, paragraph 54, defines some exemplary nonwoven scaffolds as VICRYL (a copolymer of polyglycolic acid (PGA) and polylactic acid (PLA)) having a density of 236.6 mg/cc and PDS (polydioxanone) having a density of 275.5 mg/cc. Clearly, the VICRYL and PDS nonwoven polymers show superior "high" density compared to Applicant's example on page 20 (paragraph) 88.

The '265 publication also teaches VICRYL as one of the copolymers of the nonwoven scaffold (paragraph 66). Although the '265 publication does not recite the density of VICRYL, Applicant's admission of the density of the trade-named product is sufficient for the examiner to assert that VICRYL meets Applicant's definition of a "high density" nonwoven polymer. Similarly, the '265 publication teaches "PDO" as polydixanone (called PDS in the instant specification) (paragraphs 33 and 38) and copolymer blends of PLG/PGA and "PDO" (paragraph 40). The '265 publication teaches that mesh density should be between 12-80% and preferably between 45-80% (paragraph 67). Further, the '265 application teaches that the mechanical properties of the scaffold can be altered by changing the densities of the scaffold material (paragraph 38). Thus, if Applicant considers VICRYL or polydioxanone to be "high density" nonwoven materials, then the teachings of the '265 publication clearly meets that limitation, even though it does not specifically recite the densities of the particular components. Because the recited components of VICRYL and polydioxanone are the same, the densities of the materials will be the same or nearly the same, at least enough to meet Applicant's amorphous definition of "high density" in claims 1 and 19.

New claim 34, which is dependent on claim 1, recites the scaffold of claim 1 wherein the scaffold "consists essentially" of a high density dry laid non-woven polymeric material. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at

1355 (see also, AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003). Because the instant rejection is applied under 35 USC 103(a), instant claim 34 is read as "comprising" and new claim 34 is not further limiting of claim 1. If Applicant contends that additional steps or materials in the prior art are to be excluded by the recitation of "consisting essentially of" in claim 34, Applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) (see also, Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). However, Applicant has not met this burden of showing that the addition of other materials or steps of the prior art would materially change the characteristics of Applicant's invention. See also, MPEP 2111.03.

Applicant also amends claims 1 and 19 to recite that the viable tissue is "disposed" on the tissue repaid scaffold, the viable tissue comprising viable cells capable of integrating with native tissue adjacent to the tissue repair scaffold. New claims 32 and 33 depend from claims 1 and 19 and recite wherein the viable tissue is selected from the group consisting of minced tissue, sliced tissue, and a tissue strip. The '265 publication teaches that tendon or ligament ends can be joined (e.g., by suturing, stapling, clipping, adhering, or anchoring) to ends of the implant, (paragraph 80) (compare instant claims 1 and 19). Paragraph 81 of the '265 publication also teaches that the implant may be sutured or otherwise joined to connective tissue such as the periosteum, synovium, and muscle, and wrapped around the tendon. These teachings in the '265 publication meet the amended limitations of claims 1 and 19 in that viable tissue is "disposed" on the tissue repair scaffold. Further the addition of cells to the scaffold, such as chondrocytes, is taught at p. 5, paragraph 47; and p. 11, Example 6. Example 6 of the '265 publication also teaches that primary chondrocytes were isolated from bovine shoulders as described by Buschmann et al., (paragraph 114). Buschmann et al., (J. Orthop. Res. 1992;10:745-752, especially at p. 747, column 2, second paragraph) cited only for exemplary purposes herein, teaches that saddle sections from 1-2 week old calves were diced and the chondrocytes obtained therefrom were cultured. The teachings of Buschmann et al., as incorporated and used by the '265 publication meet the limitation of using minced tissue on the scaffold, as set forth in Example 6 of the '265 publication (compare new claims 32 and 33).

The '265 publication teaches nonwoven polymeric material, but does not specifically recite that the nonwoven polymeric material is "dry-laid." Although the physical properties of the compositions produced by a dry laid process for nonwoven polymeric material versus a wet laid process for nonwoven polymeric material are equivalent, they are not necessarily identical. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also

MPEP § 2113. Applicant acknowledged this equivalency in the instant specification at paragraphs 46 and 47, page 7.

Huckle et al., teach dry laid nonwoven material for use as tissue scaffolds at p. 11, lines 25 (compare instant claims 1, 19, and 34). Example 7, pp. 20-23, teach dry laid nonwoven yarn produced by feeding it into a stuffer box type crimping unit (p. 20, line 35 to p. 21, first paragraph) (see instant claim 16). Example 7 also teaches heat-setting at p. 21, third and fourth paragraphs (see instant claim 17). Example 5 (p. 20) teaches implanting scaffold over a meniscus (see also p. 4, second paragraph) (see instant claims 1 and 19). Scaffolds comprising cells and tissue are taught at Examples 5 and 6, p. 20) (see instant claims 15 and 28). Tissue grafts are also taught at p. 5, first paragraph. Tissue scaffolds fashioned from nonwoven material that can be bioresorbable or nonbioresorbable (p. 3, lines 30-34; p. 9, lines 29-31) (compare instant claims 1 and 25). Synthetic polymers comprising polylactides, polyglycolides, and polydioxanone are taught at p. 8, lines 34-35 (see also, p. 3, last paragraph to p. 4, first paragraph) (compare instant claim 24). Random entanglement is taught as providing a large surface area for cell attachment or capture during cellular in-growth (p. 11, lines 26-27).

It would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Bowman et al., and Huckle et al., to produce a biocompatible scaffold comprising a nonwoven polymeric material from dry laid polymer to provide increased suture-pull out strength. Additionally, Huckle et al., teach that random entanglement in the nonwoven scaffold provides a large surface area for cell attachment or capture during cellular in-growth. One of skill in the art reasonably would have expected success because Huckle et al., teach dry-laid nonwoven scaffolds used in that provide superior strength for the implant. The methods of producing the nonwoven components, whether by a wet lay process (i.e. electrospinning) or by a dry laid process, are taught as equivalents by Huckle et al., and thus, one would reasonably expect to produce a strong scaffold using either or both processes.

New Claim Rejections/Objections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-8, 10-14, 16-27, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 19 have been amended to recite that the scaffold comprises a "high density" nonwoven polymeric material. Paragraph 8 of the specification generically sets forth a preferred embodiment for a "high density" nonwoven material (p.2). However, no definition of "high density" is set forth in the specification. Three densities are set forth in the specification. However, the lowest density material in the specification still meets the other physical properties of the scaffold in claims 1 and 19. It is unclear whether this lowest density is sufficient to meet the requirements of the phrase "high density." As such, the meets and bounds of the term "high density" are unclear.

The teachings in the specification provide three examples of densities. For example, a scaffold comprising 65/35 PGA/PCL foam component mated with a PDS nonwoven material having a density of 60 mg/cc and a thickness of 1mm (paragraph 88, p. 20). The suture tests for this scaffold are illustrated in Figures 6A and 6B. Figures 6A and 6B show the initial max load of N greater than 6 and initial stiffness of N about 1.5. It is noted that claims 1 and 19 also recite that the scaffold has an initial suture pull out strength (max load) of greater than about 6N and an initial modulus of elasticity (stiffness) of about 1.5 Mpa. Thus, it appears that a density of 60 mg/cc would meet the limitations of the phrase "high density" given that the other physical characteristics of the claimed scaffold meet the requisite limitations of claims 1 and 19. It is also noted that page 9 of the specification (paragraph 54) sets forth some exemplary nonwoven scaffolds that are well known in the art, including VICRYL (a copolymer of polyglycolic acid (PGA) and polylactic acid (PLA)) having a density of 236.6 mg/cc and PDS (polydioxanone) having a density of 275.5 mg/cc. Clearly, the VICRYL and PDS nonwoven polymers are "high density" compared to Applicant's example on page 20 (paragraph 88), having a density of 60 mg/cc. However, it is unclear whether the scaffold taught at p. 20 (paragraph 88) is to be considered a minimal floor limitation for a "high density" material, when it has physical properties such as suture strength (max load) and stiffness (modulus of elasticity) as shown in Figures 6A and 6B (see also claims 1 and 19) or whether the VICRYL and PDS materials are to be the standard by which to measure "high density." No lower or upper limits or any range from which one of ordinary skill could use as a floor or a ceiling to reasonably ascertain the metes and bounds of a "high density" nonwoven material are taught or disclosed in the specification or the claims as originally filed.

Claims 2-8, 10-14, 16-18, 20-27, and 32-34 are rejected for depending from rejected claims.

Provisional Obviousness-Type Double Patenting Rejection

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-8, 10-14, 16-27, and 32-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of copending Application No. 11/427,477. The instant claims are substantially identical to the claims of the co-pending '477 application. There is a common assignee and all four of the instant inventors are also inventors in the '477 application. The '477 application is a CIP of the instant Application. Although there was a restriction requirement in the instant case, it merely restricted products and methods. The conflicting claims of the instant application and the '477 application are both drawn to products. The instant claims differ in scope from the claims of the '477 application only in that the limitation of claim 9 of the '477 application has been incorporated into instant claims 1 and 19 of the instant application. Otherwise, the claims are identical. Instant claim 1 compares to claims 1 and 9 of the '477 application. Claims 2-8 and 10-14 of the instant application and the '477 application are identical. Claim 16 of the instant application is comparable to claim 18 of the '477 application. Claim 32 of the instant application is comparable to

claim 17 of the '477 application. Claims 16-18 of the instant application are comparable to claims 18-20 of the '477 application, respectively. Claim 19 of the instant application is comparable to claims 9 and 21 of the '477 application. Claims 20-27 of the instant application are comparable to claims 22-29 of the '477 application, respectively. Instant claim 33 is comparable to claim 32 of the '477 application. The claims of both applications are drawn to biocompatible tissue repair scaffolds.

It is noted that this co-pending case was unavailable to the examiner for double patenting analysis purposes as of the date of the last Office Action herein (4 May 2007). Thus, the examiner could not have reasonably foreseen the instant rejection. See MPEP 706.07(a). It is noted that the co-pending application shares four inventors in common, along with the same assignee. It follows that Applicant was fully aware of the co-pending application.

This is a provisional obviousness-type double patenting rejection.

Conclusion

NO CLAIM IS ALLOWED.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMW/
AU 1647

/Manjunath N. Rao, /

Supervisory Patent Examiner, Art Unit 1647